UNITED STATES DISTRICT COURT EASTERN DISTRICT OF VIRGINIA ALEXANDRIA DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC.,		
Plaintiffs,	Case No	1:25-cv-163
v.		
REJUVALASE MEDSPA, LLC,		
Defendant.		

COMPLAINT

Plaintiffs Novo Nordisk A/S ("NNAS") and Novo Nordisk Inc. ("NNI") (collectively, "Plaintiffs" or "Novo Nordisk") file their complaint against Rejuvalase Medspa, LLC ("Defendant") for false advertising and unfair and deceptive trade practices and seek injunctive and other relief. Plaintiffs allege as follows on actual knowledge with respect to themselves and their own acts and on information and belief as to all other matters.

INTRODUCTION

- 1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.
- 2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for those living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic® (semaglutide) injection and Rybelsus® (semaglutide) tablets for adults with type 2 diabetes and Wegovy® (semaglutide) injection for chronic weight management.

- 3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide.
- 4. Novo Nordisk is also the only company authorized to identify its FDA-approved semaglutide medicines using the trademarks Ozempic[®], Wegovy[®], and Rybelsus[®].
- 5. The FDA has not approved any generic versions of semaglutide medicines. To the contrary, the FDA has sent warning letters to companies that claimed that their Unapproved Products have the "same active ingredient as Ozempic, Rybelsus, and Wegovy," noting that Ozempic® and Wegovy® are the only "two injectable semaglutide products FDA-approved for the U.S. market."
- 6. This action is brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 et seq. and related state law arising out of Defendant's acts of false advertising and unfair and deceptive trade practices.
- 7. Defendant markets and sells to patients compounded drug products that purport to contain semaglutide.
- 8. Even though such compounded drug products have not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are FDA-approved or the same as, or equivalent to, Novo Nordisk's FDA-approved semaglutide medicines.

¹ FDA – Warning Letter to Ozempen.com, MARCS-CMS 684435 — JUNE 24, 2024, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-

 $^{06242024\#:\}sim: text=WARNING\%20LETTER\&text=As\%20 discussed\%20 below\%2C\%20 FDA\%20 has, new\%20 drugs s\%20 and \%20 misbranded\%20 drugs.$

9. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

THE PARTIES

- 10. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark.
 - 11. Novo Nordisk developed the Ozempic[®], Wegovy[®], and Rybelsus[®] medicines.
- 12. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale, and sell Ozempic[®], Wegovy[®], and Rybelsus[®] medicines in the United States.
- 13. NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business in Plainsboro, New Jersey.
- 14. NNI promotes, offers, and sells Novo Nordisk's Ozempic[®], Wegovy[®], and Rybelsus[®] medicines throughout the United States, including in this District.
- 15. Defendant is a limited liability company with a registered business address at 60 Susa Drive, Suite 123, Stafford, Virginia 22554 in this District.
- 16. Defendant markets and sells compounded drug products that purport to contain semaglutide, but that have not been approved by the FDA ("Unapproved Compounded Drugs").
- 17. Defendant falsely claims or otherwise misleadingly suggests that its Unapproved Compounded Drugs are the same as or equivalent to the Ozempic[®], Wegovy[®], and Rybelsus[®] medicines.

JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction over the Lanham Act cause of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 1338(a).

- 19. The Court has supplemental jurisdiction over the state law cause of action pleaded herein pursuant to 28 U.S.C. § 1338(b).
- 20. Defendant is subject to personal jurisdiction in this District because Defendant has a principal place of business in Virginia.
- 21. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, markets and sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District.

NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES AND OZEMPIC®, WEGOVY®, AND RYBELSUS® TRADEMARKS

- 22. Plaintiffs use the trademarks "Ozempic," "Wegovy," and "Rybelsus" to identify and promote the FDA-approved Ozempic[®], Wegovy[®], and Rybelsus[®] medicines. NNAS's indirect, wholly-owned subsidiary, NNI, markets and sells the Ozempic[®], Wegovy[®], and Rybelsus[®] medicines in the United States.
- 23. The Ozempic® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.
- 24. The Ozempic[®] medicine also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease.
- 25. The Wegovy[®] medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged \geq 12 years with obesity, and some adults with overweight and weight-related medical problems, along with a reduced calorie diet and increased physical activity.
- 26. The Wegovy® medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as

"cardiovascular" death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.

- 27. The Rybelsus® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.
- 28. The Ozempic®, Wegovy®, and Rybelsus® medicines have been extensively studied in clinical trials and are FDA-approved.
- 29. Each of the Ozempic[®], Wegovy[®], and Rybelsus[®] medicines has a unique safety and efficacy profile which is set forth in its respective product label.
- 30. The Ozempic[®], Wegovy[®], and Rybelsus[®] medicines are prescription-only medicines that should be prescribed only in direct consultation with, and under the supervision of, a licensed healthcare professional.

DEFENDANT'S SALE OF UNAPPROVED COMPOUNDED DRUGS

- 31. Novo Nordisk does not sell its FDA-approved semaglutide medicines, Ozempic[®], Wegovy[®], and Rybelsus[®], to Defendant for resale or redistribution.
- 32. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide.
 - 33. The FDA has not approved Defendant's Unapproved Compounded Drugs.
- 34. On information and belief, the Unapproved Compounded Drugs Defendant markets and sells are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.
- 35. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a

licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."²

- 36. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients."
- 37. The FDA has further stated that compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks."⁴
- 38. As the FDA has explained, "[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug."⁵
- 39. The process used to produce most "semaglutide" used in compounding is fundamentally different from the process used to produce the semaglutide in Novo Nordisk's FDA-approved medicines. Novo Nordisk manufactures the semaglutide in its medicines, pursuant to its FDA approval, in yeast cells under a closely controlled multistep process that uses recombinant DNA technology. Most compounded "semaglutide," however, uses a "semaglutide" manufactured via chemical synthesis. The chemical synthesis process, which is

 $^{^2\,}Human\,Drug\,Compounding,\,https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.$

³ Compounding Laws and Policies, https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.

⁴ Compounding and the FDA: Questions and Answers, https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.

⁵ FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm medium=email&utm source=govdelivery.

not used for the semaglutide in any FDA-approved semaglutide medicines, has resulted in new impurities, higher levels of known impurities, immunogenicity concerns, and potential stability issues in tested samples of compounded "semaglutide."

- 40. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded "semaglutide" products.⁷ In several instances, patients mistakenly administered five to 20 times more than the intended dose of compounded "semaglutide."
- 41. The FDA has stated that the containers and packaging (including multidose vials and prefilled syringes) used by compounders, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors.
- 42. A previous publication from the Journal of the American Pharmacists Association also highlighted errors where patients accidentally self-administered doses of compounded "semaglutide" up to ten times greater than the intended amount.⁸
- 43. The FDA has issued guidance on its "Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," which provides that: (1) "compounded drugs are not FDA-approved"; (2) use of compounded drugs containing "semaglutide" "can be risky for patients, as unapproved versions do not undergo FDA's review for safety, effectiveness and quality"; and (3) "FDA has received reports of adverse events related to compounded versions of semaglutide

⁶ Morten Hach *et al*, Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-On GLP-1 Polypeptide Drugs, Pharm. Res., (Oct. 8, 2024), *available at* https://pubmed.ncbi.nlm.nih.gov/39379664/.

⁷ FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.

⁸ Joseph E. Lambson et al, *Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—Case Series*, 63 J. Am. Pharmacists Assc'n 5 (2023), available at https://www.japha.org/article/S1544-3191(23)00231-5/abstract.

However, federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA, so it is likely that adverse events from compounded versions of these drugs are underreported."

<u>DEFENDANT'S FALSE ADVERTISING IN CONNECTION WITH ITS</u> SALE OF UNAPPROVED COMPOUNDED DRUGS

- 44. Despite the foregoing, Defendant has made false and misleading representations to patients regarding the nature of its Unapproved Compounded Drugs.
- 45. Defendant has falsely advertised its Unapproved Compounded Drugs by making statements that describe the Ozempic[®], Wegovy[®], and Rybelsus[®] medicines but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs.
- 46. Defendant falsely claims or implies that its Unapproved Compounded Drugs are FDA-approved and are equivalent to, contain the same semaglutide as, and have been subject to the same kinds of clinical trials and testing for safety, efficacy, and quality as the FDA-approved Ozempic[®], Wegovy[®], and Rybelsus[®] medicines.
 - 47. On its website, Defendant has stated that its "semaglutide" is FDA approved.

FDA-APPROVED

SEMAGLUTIDE: A COMPREHENSIVE APPROACH
TO TYPE 2 DIABETES AND WEIGHT MANAGEMENT

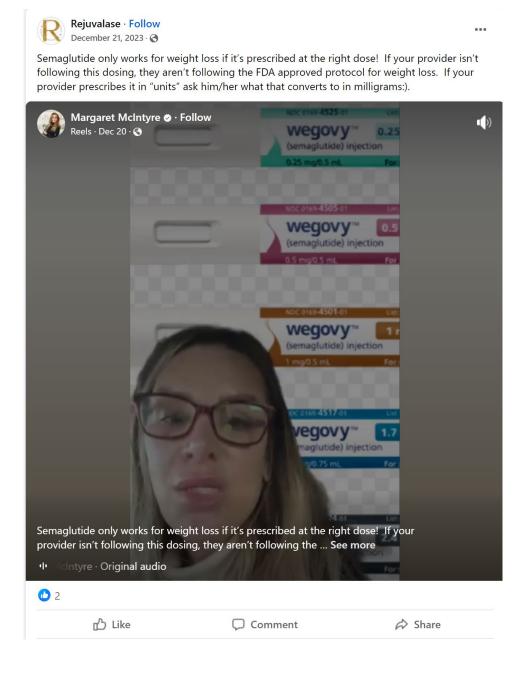
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⁹ FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss.

UNDERSTANDING SEMAGLUTIDE

Semaglutide is a glucagon-like peptide-1 (GLP-1) agonist that has carved a niche for itself in the realm of type 2 diabetes management. This class of drugs imitates the function of the naturally occurring hormone GLP-1, reducing blood sugar levels and suppressing appetite. Semaglutide has also recently been approved for use in managing chronic weight, expanding its therapeutic portfolio.

48. On its Facebook page, Defendant has claimed that it offers an FDA-approved medication and, further, indicated or implied that it offers Wegovy[®].



49. On its website, Defendant has advertised its Unapproved Compounded Drugs by claiming that "[s]emaglutide is the active ingredient in the well-known medication brands, Ozempic and Wegovy."

SEMAGLUTIDE | 3 MONTH SUPPLY | TIER I

\$1,500

The struggle of losing weight despite diet and exercise can feel defeating. Excessive body fat's physical toll on your body is often coupled with an emotional toll if you are at least 20 lbs. If you are overweight and/or have a BMI of 25 or greater, you may be a candidate for our Semaglutide weight loss injections.

Semaglutide is the active ingredient in the well-known medication brands, Ozempic and Wegovy.

- 50. The statements in paragraphs 47–49 above are all false and misleading.
- 51. Defendant's false representations mislead patients into believing, incorrectly, that the drug with "semaglutide" offered by Defendants is the same as the Ozempic[®], Wegovy[®], and Rybelsus[®] medicines that have been reviewed and approved by the FDA for safety and effectiveness.
- 52. Defendant's false representations mislead patients into believing, incorrectly, that the Unapproved Compounded Drugs offered by Defendant are as safe and effective as the

Ozempic[®], Wegovy[®], and Rybelsus[®] medicines that have been reviewed and approved by the FDA for safety and effectiveness.

- 53. Defendant's false representations mislead patients into believing, incorrectly, that the Unapproved Compounded Drugs offered by Defendant have been subject to clinical studies and trials or have otherwise achieved therapeutic outcomes attributable to the Ozempic[®], Wegovy[®], and Rybelsus[®] medicines.
 - 54. The FDA approves only complete medications, not molecules like semaglutide.
- 55. The FDA has not evaluated, let alone approved as safe and effective, Defendant's Unapproved Compounded Drugs.
- 56. The FDA has not reviewed the semaglutide allegedly in Defendant's Unapproved Compounded Drugs as equivalent in safety, effectiveness, or quality to Novo Nordisk's medicines.
- 57. On information and belief, Defendant has not conducted any placebo-controlled or clinical studies on its Unapproved Compounded Drugs and is instead misleadingly referring to studies conducted on Plaintiffs' FDA-approved Ozempic® and Wegovy® medicines.
- 58. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits.
- 59. There is no need for Defendant to use the Ozempic[®] and Wegovy[®] trademarks to advertise or promote its Unapproved Compounded Drugs purporting to contain "semaglutide," other than to trade on the reputation of Plaintiffs and to create confusion in the marketplace or mislead the public regarding the origin, identity, or source of Defendant's Unapproved Compounded Drugs.

- 60. Defendant's false and misleading representations are likely to cause mistake and deception in the marketplace.
- 61. Defendant's false and misleading representations are also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.¹⁰
- 62. On information and belief, unless enjoined by this Court, Defendant will continue to falsely advertise its products as being, equivalent to, or associated with the Ozempic[®] and Wegovy[®] medicines, all in violation of Plaintiffs' rights.
- 63. On information and belief, unless enjoined by this Court, Defendant's conduct will continue to cause mistake and deception.

FIRST CAUSE OF ACTION

Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

- 64. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.
- 65. Defendant's above-described practices constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

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¹⁰ See, e.g., Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs, WFAA, https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested."); FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm_medium=email&utm_source=govdelivery ("Compounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness.").

- 66. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and qualities of Defendant's business practices and products, as set forth above.
- 67. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or whom Defendant is trying to persuade to purchase its drugs) information that makes false or misleading statements, including those described herein.
- 68. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.
- 69. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.
- 70. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.
- 71. By reason of Defendant's above-described acts, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation.
- 72. Because Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant, Plaintiffs are entitled to preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

- 73. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.
- 74. This case is exceptional, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

Violation of Virginia Consumer Protection Act Va. Code Ann. § 59.1-196 et seq.

- 75. Plaintiffs reallege and incorporate each allegation in the preceding paragraphs of this Complaint as though fully set forth here.
- 76. The above-described acts of Defendant constitute fraudulent acts or practices in violation of the Virginia Consumer Protection Act ("VCPA").
- 77. The VCPA prohibits "fraudulent acts or practices committed by a supplier in connection with a consumer transaction." Va. Code Ann. § 59.1-200(A). These fraudulent acts include: misrepresenting goods or services as those of another; misrepresenting the source, sponsorship, approval, or certification of goods or services; misrepresenting the affiliation, connection, or association of the supplier, or of the goods and services, with another; and misrepresenting that goods or services have certain qualities, characteristics, ingredients, uses, or benefits. VA. Code Ann. §§ 59.1-200(A)(1), 59.1-200(A)(2), 59.1-200(A)(3), 59.1-200(A)(5).
- 78. The above-described acts are made in the conduct of Defendant's business, trade or commerce, and are fraudulent and deceptive as defined by the VCPA, because Defendant is falsely passing off its goods as those of Plaintiffs, causing likelihood of confusion as to source, sponsorship, approval or certification of its goods, and causing likelihood of confusion as to

affiliation, connection, or association with Plaintiffs' goods, and falsely passing off its Unapproved Compounded Drugs as FDA approved weight loss drugs.

- 79. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.
- 80. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.
- 81. The above-described acts of Defendant have caused Plaintiffs to suffer an ascertainable loss, including injury to Plaintiffs' business reputation.
 - 82. Defendant has unfairly profited from the actions alleged.
- 83. By reason of Defendant's acts, Plaintiffs' remedy at law is not adequate to compensate for the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to preliminary and permanent injunctive relief in addition to monetary relief in the form of disgorgement of Defendant's profits.
- 84. By reason of the willfulness of Defendant's above-described acts, Plaintiffs are entitled to treble damages under Va. Code Ann. § 59.1-204(A).

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

- 1. That the Court enter a judgment against Defendant that Defendant has:
 - a. Engaged in false and misleading advertising and promotion, in violation of 15
 U.S.C. § 1125(a);
 - b. Engaged in unfair and deceptive trade practices under the Virginia Consumer Protection Act, Va. Code Ann. § 59.1-196 *et seq*.
- 2. That the Court declare that each of the above acts was willful.

- 3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:
 - a. using the Ozempic[®] and Wegovy[®] marks, including (i) use in any manner likely to cause confusion or mistake, to deceive, or otherwise infringe Novo Nordisk's rights in the Ozempic[®] and Wegovy[®] marks, or (ii) use in connection with the advertising, marketing, sale, or promotion of any Unapproved Compounded Drugs; and,
 - b. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:
 - i. are, or contain, genuine or authentic Novo Nordisk Ozempic[®], Wegovy[®],
 or Rybelsus[®] medicines;
 - ii. are sponsored by or associated with Novo Nordisk;
 - iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;
 - iv. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes, including by relying on or making reference to clinical trial results for Novo Nordisk's medicines;
 - v. achieve or have been shown or proven to achieve therapeutic results,
 effects, or outcomes similar or identical to Novo Nordisk's medicines or

- are interchangeable with or equivalent to genuine Novo Nordisk medicines;
- vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or
- vii. contain any ingredient (including semaglutide) that is supplied by Novo
 Nordisk, is approved by the FDA, or is the same as any ingredient in any
 Novo Nordisk medicine.
- c. engaging in unfair and deceptive trade practices with respect to Novo Nordisk's Ozempic[®], Wegovy[®], or Rybelsus[®] medicines; and
- d. engaging in deceptive acts or practices with respect to Novo Nordisk's Ozempic[®], Wegovy[®], or Rybelsus[®] medicines.
- 4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.
- 5. That the Court award Plaintiffs monetary relief in the form of disgorgement of Defendant's profits for Defendant's false advertising and unfair and deceptive trade practices with respect to Novo Nordisk's Ozempic[®], Wegovy[®], or Rybelsus[®] medicines and that this

monetary relief be trebled due to Defendant's willfulness, in accordance with 15 U.S.C. § 1117 and any applicable state laws.

6. That the Court order Defendant to account for and disgorge to Plaintiffs all

amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful

actions with respect to Novo Nordisk's Ozempic®, Wegovy®, or Rybelsus® medicines.

7. That the Court award Plaintiffs punitive damages by reason of Defendant's

willful unlawful actions with respect to Novo Nordisk's Ozempic®, Wegovy®, or Rybelsus®

medicines.

8. That the Court award Plaintiffs pre-judgment and post-judgment interest on all

damages.

9. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15

U.S.C. § 1117 and any other applicable provision of law.

10. That the Court award Plaintiffs the costs of suit incurred herein.

11. That the Court grant such other or further relief as the Court may deem just and

proper.

January 30, 2025

Respectfully submitted,

By: *s/Connor Kelley*

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